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FRESENIUS MEDICAL CARE - DESERT INN	**1750 E DESERT INN RD #100 LAS VEGAS, NV 89109**

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V 000	INITIAL COMMENTS This Statement of Deficiencies was generated as the result of an Medicare recertification survey conducted at your facility on 11/20/08. The findings and conclusions of any investigation by the Health Division shall not be construed as prohibiting any criminal or civil investigation, actions or other claims for relief that may be available to any party under applicable federal, state or local laws. The total census was 153. 15 clinical records were reviewed. 5 patients were interviewed. The following regulatory deficiencies were identified.	V 000		
V 111	494.30 INFECTION CONTROL The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas. This STANDARD is not met as evidenced by: Based on observation, the facility failed to provide a sanitary environment. Findings Include: On 11-18-08 during the initial tour of the facility, trash and packaging materials were observed in the dry storage area, cluttering the floor. It was noted that no activity was occurring in the room during this observation.	V 111		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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V 111	Continued From page 1 On 11-18-08 during the initial tour of the facility, the acid room (room where storage tanks are located) had rags left on top of the equipment and other debris on the floor within the room. It was noted that no maintenance or activity was occurring in the room during this observation.	V 111		
V 114	494.30(a)(1)(i) CDC RR-5 AS ADOPTED BY REFERENCE A sufficient number of sinks with warm water and soap should be available to facilitate hand washing. This STANDARD is not met as evidenced by: Based on observation and interview the facility failed to provide a sufficient number of sinks to facilitate hand washing. Findings include: Note: This standard requires that sinks are easily accessible and readily available in the patient treatment area and other appropriate areas such as the home training rooms. On 11/19/08 during observation of the home training areas, it was observed that two training rooms are utilized for training of home peritoneal dialysis patients. One of the training rooms has a hand sink. The other adjacent room is not equipped with a sink for hand washing. Upon interviewing staff about how they would wash their hands, they responded by indicating that they would wash their hands in the room with the sink and then exit this room and enter the training room without the sink. Both rooms have	V 114		

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V 114	Continued From page 2 doors with latching hardware that requires staff to touch and re-touch the handles when entering and leaving the rooms.	V 114		
V 121	494.30(a)(4)(i) PROCEDURES FOR INFECTION CONTROL [The facility must demonstrate that it follows standard infection control precautions by implementing-] (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the- (i) Handling, storage and disposal of potentially infectious waste; This STANDARD is not met as evidenced by: Based on observation the facility failed to properly dispose of potentially infectious waste. Findings include: On 11-19-08 during inspection of the laboratory refrigerator, approximately 15 urine specimen cups with varying amounts of urine were found stored in the refrigerator. Some of the urine cups were dated indicating the specimens were collected as early as 11/5/08.	V 121		
V 255	494.40(a) ANSI/AAMI RD52:2004 AS ADOPTED BY REFERENCE 7.2 Microbial monitoring methods 7.2.1 General: repeat cultures Cultures should be repeated when bacterial counts exceed the allowable levels. If culture growth exceeds permissible standards, the water system and dialysis machines should be cultured weekly until acceptable results are obtained.	V 255		

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V 255	Continued From page 3	V 255		

Additional samples should be collected when there is a clinical indication of a pyrogenic reaction or septicemia, and following a specific request by the clinician or the infection control practitioner.

If repeat cultures are performed after the system has been disinfected (e.g., with formaldehyde, hydrogen peroxide, chlorine, or peracetic acid), the system should be flushed completely before collecting samples. Drain and flush storage tanks and the distribution system until residual disinfectant is no longer detected before collecting samples.

This STANDARD is not met as evidenced by:
Based on interview and review of documentation provided, the facility failed to ensure cultures were repeated when bacterial counts exceed the allowable levels in a timely manner.

Findings include:

"Policy Name: RO Permeate Culture Sampling -Revised 8/2/05

1. Purpose: The water used for dialysis is cultured to determine the effectiveness of the disinfection process and to maintain bacterial growth at or below AAMI Standards.

II. Performed by: Biomedical, Technical and Clinical Associates who had demonstrated satisfactory competency.

IV. Policy:

A. Samples will be collected from sample ports of equipment as recommended by the CDC (Center

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V 255	Continued From page 4 for Disease Control), AAMI (Association for the Advancement of Medical Instrumentation) and equipment manufacturer. Cultures will be drawn prior to routine disinfection process or monthly, which ever occurs first. If results are equal to. or greater than the action levels set by AAMI, 50CFU/ml, or 1 EU/ml, corrective measures shall be taken to reduce the levels into an acceptable range. E. Package all samples for shipping per laboratory procedure. F. Report positive culture results that exceed action levels to the Facility Manager, follow the appropriate Culture Testing Process Flowchart, Medical Director is informed of culture results exceeding the AAMI standards through CQI (Continuous Quality Improvement) committee. The Medical Director must sign RenaLab Microbiological Summary Report and CQI Culture Trending Log. " Interview On 11/19/08 in the afternoon, an interview with the biomedical technician was conducted. The technician indicated when the culture results were above 50 CFU/ml (colony forming units per milliliter) a repeat culture was to be redrawn in 48 hours. Review of the documentation provided by the facility identified the following results: RO #1 On 2/8/08 the RO #1 colony count result was 122 CFU/ml. On 2/14/08, the RO #1 was recultured	V 255		

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V 255	Continued From page 5 with a colony count result of 34 CFU/ml. On 4/3/08, the RO #1 weekly draw was over 200 CFU/ml. On 4/6/08, the RO #1 was recultured with the colony count result of 50 CFU/ml. On 4/9/08, the RO #1 was recultured with the colony count less than 2 CFU/ml. On 6/21/08, the RO #1 colony count was over 200 CFU/ml. On 6/25/08, the RO #1 reculture result was less than 2 CFU/ml. On 7/12/08, the RO #1 colony count was more than 200 CFU/ml. On 7/18/08, the RO #1 the reculture result was less than 2 CFU/ml. On 9/6/08, the RO #1 colony count was 78 CFU/ml. On 9/10/08, the RO #1 colony count was less than 2 CFU/ml. There was no documented evidence to verify the technician recultured the RO #1 within 48 hours. Holding Tank On 2/8/08, the holding tank colony count was more than 60CFU/ml. On 2/14/08, the holding tank was recultured with a result of 46 CFU/ml. On 4/3/08, the holding tank colony count was more than 200 CFU/ml. On 4/6/08, the holding tank reculture result was more than 76 CFU/ml. On 4/9/08, the holding tank was recultured with a result of less than 2 CFU/ml. On 5/3/08, the holding tank colony count was 156 CFU/ml. On 5/7/08, the holding tank reculture result was less than 2 CFU/ml. On 6/21/08, the holding tank colony count was over 200 CFU/ml. On 6/25/08, the holding tank reculture result was less than 2 CFU/ml. On 7/12/08, the holding tank colony count was 110 CFU/ml. On 7/18/08, the holding tank reculture result was less than 2 CFU/ml.	V 255		

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V 255	Continued From page 6 There was no documented evidence to verify the technician recultured the Holding Tank within the 48 hour timeframe. There was no documented evidence to verify the Medical Director was notified after the reculture results were over 76 CFU/ml. Unit Return On 6/21/08, the unit return colony count was over 200 CFU/ml. There was no documented evidence to verify a reculture was conducted on the unit return. There was no documented evidence to verify the Medical Director was notified of the colony count over 200 cfu/ml.	V 255		
V 402	494.60(a) PHYSICAL ENVIRONMENT: BUILDING The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public. This STANDARD is not met as evidenced by: Based on observation, the facility failed to maintain the structural integrity of the facility to ensure safety. Findings Include: Note: This standard requires that all buildings must be maintained free from defects and/or hazards to ensure safety and functionality. Integrity of all surfaces must be intact, clean and free from damage. On all days of the survey, the floor in the acid room (room where storage tanks are located) was	V 402		

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V 402	Continued From page 7 observed to be bare concrete that was damaged, pitted and stained.	V 402		
V 451	494.70 PATIENTS' RIGHTS The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights. This STANDARD is not met as evidenced by: Based on interview and review of facility policies, the facility failed to clearly inform patients (or their representatives) of their responsibilities during treatment. Findings Include: On 11-18-08 and 11-20-08, interviews with patients' family members and representatives indicated that the facility had recently changed its policy concerning visitors in the treatment area. The pertinent part of the new policy only allowed visitors to remain in the treatment area for 15 minutes of each hour. On 11-18-08 interview with facility staff confirmed that the facility had indeed changed its policy. However, the new policy was not in writing or clearly defined. In fact the clinical manager described the process by which the new policy information was dissiminated to visitors as an individual agreement with certain visitors. Review of the facility's policy #138-020-060 indicates the following: Exhibit A, "You have the right to: Clear information about facility policies" - in addition the policy indicates the following rights, "Be informed of facility policies regarding patient care, including policies about visitors, eating and restroom use during treatment...". Within this	V 451		

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V 451	Continued From page 8 policy there was no mention of the 15 minute rule. Patient family members and representatives expressed frustration with the new policy and wondered whether it was being implemented fairly.	V 451		
V 503	494.80(a)(2) ASSESSMENT CRITIERIA [The patient's comprehensive assessment must include, but is not limited to, the following:] (2) Evaluation of the appropriateness of the dialysis prescription, This STANDARD is not met as evidenced by: Based on interview, and clinical records, the facility failed to ensure the comprehensive assessment included an evaluation of the appropriateness of the dialysis prescription for 3 of 15 patients in the sample. (#11, #3, #6) Findings include: Hemodialysis Procedure Manual- Clincal Services Auto Flow Dialysate Procedure dated 7/22/02 Purpose: To appropriately match dialysate flow automatically to dialyzer performance while conserving dialysate during the interdialytic periods. Patient #11 The patient was admitted with the following diagnoses: end stage renal disease, hypertension and diabetes.	V 503		

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V 503	Continued From page 9 The Patient was on a F180 non re-use dialyzer. The hemodialysis prescription indicated the blood flow rate was 400 and the dialysate flow rate was 600. The patient's access site was a catheter located in the left subclavian vein. The Standard orders, dated 11/3/08 revealed: Set Automatic Dialysate Flow Rate= 1.5 times the blood flow rate. On 11/3/08, the blood flow rate was between 300-202 with a dialysate flow rate of 500 throughout the treatment of 240 minutes. On 11/5/08, the blood flow rate was between 300-297 with a dialysate flow rate of 500 throughout the treatment of 240 minutes. On 11/7/08, the blood flow rate was between 350-297 with a dialysate flow rate of 500 throughout the treatment of 240 minutes. On 11/10/08, the blood flow rate was between 305-297 with a dialysate flow rate of 500 throughout the treatment of 240 minutes. On11/12/08, the blood flow rate was between 305-297 with a dialysate flow rate of 500 throughout the treatment of 240 minutes. There was no documented evidence to verify the reason the dialysis flow rate did not equal 1.5 times the blood flow rate. Patient #3 The patient was admitted on 2/21/03 with a diagnosis: end stage renal disease. The Patient was on a F180 non re-use dialyzer.	V 503		

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V 503	Continued From page 10 The hemodialysis prescription indicated the blood flow rate was 400 and the dialysate flow rate was 600. The patient's access site was an A-V Graft located on the left upper arm. The Standard orders, dated 11/6/08 revealed: Set Automatic Dialysate Flow Rate= 1.5 times the blood flow rate. On11/6/08, the blood flow rate was between 300-230 with a dialysate flow rate of 500 throughout the treatment of 210 minutes. There was no documented evidence to verify the reason the dialysis flow rate did not equal 1.5 times the blood flow rate. Patient #6 The patient was admitted on 11/5/2005 with a diagnosis: end stage renal disease, hypertension, and diabetes. The Patient was on a F180 non re-use dialyzer. The hemodialysis prescription indicated the blood flow rate was 450 and the dialysate flow rate was 800. The patient's access site was graft located on the left not specified. The Standard orders, dated 11/6/08 revealed: Set Automatic Dialysate Flow Rate= 1.5 times the blood flow rate. On11/3/08, the blood flow rate was between 451-459 with a dialysate flow rate of 500 throughout the treatment of 245 minutes. On11/3/08, the blood flow rate was between 448-454 with a dialysate flow rate of 500 throughout the treatment of 245 minutes. On 11/19/08An interview with the area manager and clinical manager indicated the machine would	V 503		

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V 503	Continued From page 11 automatically adjust thediaylsate flow according to the blood flow rate. The machine did not automatically adjust the rate.	V 503		
V 556	494.90(b)(1) IMPLEMENTATION OF THE PATIENT PLAN OF CARE The patient's plan of care must- (i) Be completed by the interdisciplinary team, including the patient if the patient desires; and (ii) Be signed by the team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure the patient's plan of care was signed by the team members and the patient or designee for 2 of 15 patients in the sample. (#3, #2) Findings include: Patient #3 The patient was admitted on 2/21/03 with a diagnosis: end stage renal disease. The Patient was on a F180 non use dialyzer. The hemodialysis prescription indicated the blood flow rate was 400 and the dialysate flow rate was 600. The patient's access site was an A-V Graft located on the left upper arm. Review of the clinical record revealed the last short term care plan was dated 5/4/07. An interview with the clinical manager indicated	V 556		

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V 556	Continued From page 12	V 556		

the short term care plans were located in the computer. The interdisciplinary team members were able to sign their names in the computer.

The clinical manager generated the short term care plan from the computer, dated 1/19/08 there was no documented evidence the nephrologist and patient signed the short term care plan.

The clinical manager generated an additional short term care plan from the computer, the plan was not dated and the registered dietician, nephrologist and patient did not sign the care plan.

Patient #2

The patient was admitted on 1/6/04 with the following diagnoses: diabetes, and end stage renal disease.
The patient was on a F180 non use dialyzer. The hemodialysis prescription indicated the blood flow rate was 400 and the dialysate flow rate was 600. The patient's access site was an A-V fistula located on the left upper arm.

The most current short term care plan was dated 6/12/08 with a recommendation to update care plan in one month related to being unstable. There was no documented evidence to verify a updated care plan was established by the interdisciplinary team. The patient was presently receiving dialysis treatment at the facility.

On 11/19/08 in the afternoon, an interview with the clinical manager revealed the patient had a number of hospitalizations in 4/24/08 for 43 days, 6/14/08 for 4 days, 7/12/08 for 4 days and on 8/12/08 for 29 days. There was no documented

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V 556	Continued From page 13 evidence to verify the patient's care plan was updated.	V 556		